

II. REMARKS

Claims 10, 14 to 18, 21, 23, and 24 are pending. Claims 1 to 9, 11 to 13, 19, 20, and 22 were previously cancelled without prejudice to, or disclaimer of, the underlying subject matter. Claims 21 and 24 are amended. Support for the claim amendments may be found in the specification as originally filed. *See, for example*, page 100, line 19 to page 123, line 3. Therefore, no new matter is added by way of these amendments.

Claim Rejection under 35 U.S.C. § 112, second paragraph:

Claim 21 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly “being indefinite.” Office Action at page 2. Claim 21 is amended to a recombinant nucleic acid construct encoding the isolated transcription factor of claim 10. Therefore, Applicants respectfully submit that this rejection is moot and request its withdrawal.

Claim Rejections under 35 U.S.C. § 112, first paragraph:

Claim 24 was rejected under 35 U.S.C. § 112, first paragraph, for allegedly “failing to comply with the written description requirement.” Office Action at page 3. Applicants respectfully traverse.

According to the Examiner, the specification does not provide written description support for plants comprising nucleic acid molecules of the present invention without, for example, promoters, non-translated sequences, etc. The Examiner also alleges that the specification does not support the genus of modified plants claimed. Applicants respectfully submit that the Examiner’s understanding of the teachings of the specification is inaccurate.

The specification as filed teaches that one method by which transformed plants can be created is using vectors that contain exogenous genetic material. *Specification* at page 101, lines 18 to 21. This vector may include regulatory elements. *Id.* at page 106, line 22 (emphasis added). In other words, the specification as filed provides written description to one of ordinary skill in the art on how to produce transformed plants comprising, for example, SEQ ID NO: 1 (exogenous genetic material), and that SEQ ID NO: 1 may or may not be associated with other elements, such as regulatory sequences. Further, the specification as filed discloses a number of plants into which the genetic material can be transferred, including maize, soybean, *Arabidopsis*, oat, sugarcane, banana, apple, and coffee. *Specification* at page 101, lines 1 to 11. In other words, the specification as filed fully supports the entire scope of claim 24 and Applicants respectfully request withdrawal of this rejection.

Claims 10, 14 to 18, 21, 23, and 24 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly “failing to comply with the enablement requirement.” Office Action at page 3. Applicants respectfully traverse.

The Examiner points to various *Wands* factors in support of her proposition that undue experimentation would be required by one of ordinary skill in the art to make and use the invention. Office Action at pages 4 to 7. Applicants respectfully submit that the Examiner’s analysis of the *Wands* factors with respect to claims 10, 14 to 18, 21, 23, and 24 is incorrect.

The Examiner states that in order to practice the invention, one of skill in the art must know *a priori* that SEQ ID NO: 1 has transcription factor activity and that the specification provides no disclosure that SEQ ID NO: 1 has transcription factor activity. These statements are incorrect because the specification as filed clearly discloses that SEQ ID NO: 1 has transcription

factor activity. *See, for example, Specification* at page 32, lines 12 to 15. Moreover, Table A of the specification discloses that SEQ ID NO: 1 has a 100% identity to a known transcription factor. The Examiner counters by arguing that the alignment between SEQ ID NO: 1 and the known transcription factor is “only 83.4%”. Office Action at page 4. The Examiner relies on Bork *et al.* (*J. Mol. Biol.* **283**, 707 – 725, 1998) to support her position that gene function and protein function based on alignments is unpredictable. *Id.* at page 5. The Examiner also states that because an “important” factor such as the K box is not present in SEQ ID NO: 1, one of skill in the art would doubt that SEQ ID NO: 1 functions as a transcription factor. *Id.*

As the Examiner is aware, “a ‘rigorous correlation’ need not be shown in order to establish practical utility; ‘reasonable correlation’ is sufficient.” *See, Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565 (Fed. Cir. 1996), emphasis added. “An Applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of the compound or composition, arguments or reasoning, documentary evidence, or any combination thereof.” M.P.E.P. § 2107.03, at page 2100-43. In other words, even if, arguendo, the alignment between SEQ ID NO: 1 and the known transcription factor is 83.4%, and not 100%, this level of correlation is reasonable to one of ordinary skill in the art.

Moreover, with respect to the alleged absence of the K box in SEQ ID NO: 1, the Examiner has provided no scientific information that all transcription factors must contain K boxes. Indeed, the Examiner admits that a portion of SEQ ID NO: 1 contains another important transcription factor, namely a MADS box. Office Action at page 5. In other words, the Examiner has provided no evidence to show that one of ordinary skill in the art would reasonably doubt that SEQ ID NO: 1 encodes a transcription factor.

The Examiner goes on to state that single or multiple substitutions or deletions can alter biochemical function in many instances, albeit not all. Office Action at page 5, emphasis added. According to the Examiner, the effects of such changes are largely unpredictable. *Id.* Therefore, according to the Examiner, it would require undue experimentation for one of ordinary skill in the art to make and use the invention. Applicants respectfully disagree because one of ordinary skill in the art would be reasonably able to predict which changes would result in loss of function. As the M.P.E.P. clearly states, “(i)f one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art.” M.P.E.P. § 2164.03. For example, the specification as filed provides ample knowledge of “conservative” changes. *Specification* at page 58, line 14 to page 60, line 7. In other words, one of ordinary skill in the art can readily anticipate the effects of substitutions or deletions on the nucleic acid molecules of the claimed invention. Further, Applicants respectfully remind the Examiner that the test of enablement is not whether *any* experimentation is necessary, but whether, if experimentation is necessary, it is *undue*. *In re Angstadt*, 537 F.2d 498, 504 (C.C.P.A. 1976); M.P.E.P. § 2164.01.

Applicants also respectfully remind the Examiner that in order to make an enablement rejection under 35 U.S.C. § 112, first paragraph, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993). Further, the utilities disclosed in the specification must be accepted as factually sound unless the USPTO cites information that undermines the credibility of the assertion. *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995). Applicants respectfully submit that the Examiner has not satisfied her burden. By contrast, Applicants submit that the

specification as filed provides sufficient disclosure to enable one of ordinary skill in the art to make and use the invention without undue experimentation. Therefore, Applicants respectfully request withdrawal of the enablement rejection of claims 10, 14 to 18, 21, 23, and 24 under 35 U.S.C. § 112, first paragraph.

III. CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application is now in condition for allowance, and respectfully request notice of such. The Examiner is encouraged to contact the undersigned at 202-942-5746 if any additional information is necessary for allowance.

Respectfully submitted,

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